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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,195	09/12/2000	Howard R. Levin	3659-17	6619

7590 11/19/2002

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/660,195

Applicant(s)

LEVIN ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 10 September 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 10 September 2002 have been accepted. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. Claims 1-15 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the isolation between the pressure sensor and the blood pump. The language of the claim fails to set forth any specific structural relationship between the location of the pressure sensor and the pump.

3. Claim 4 recites the limitation "the filtered fluid passages" in line 2. It is unclear whether applicant intends to claim a second filtered fluid passage in addition to the previously recited filtered fluid passage. There is insufficient antecedent basis for plural filtered fluid passages in the claim.

4. Claim 20 recites the limitation "the blood return passage" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 7, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,838,865 to Flank et al. Flank discloses a blood handling cartridge with inlet tubing 11, pressure measuring devices 15, 24 that may operate pizelectrically and comprises electrical connections 117, 118 (FIG 15, column 8, lines 42-57), pump segment 10 that defines a blood passage that is engaged by a pump, and outlet tubing 11' (see FIG 3, column 5, lines 45-67). The system disclosed by Flank further includes a dialyzer/blood filter 27 in fluid communication with and connected to the blood cartridge (see FIG 3), and a pressure gauge 24a in the filtered fluid passage 28a (see FIG 4). With regard to applicant's recitation of the manner in which the pressure sensor operates (producing an electric voltage signal), and disposal of the device, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5, 6, 10, 11, 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,838,865 to Flank in view of US 6,171,253 to Bullister et al. Flank discloses the apparatus as claimed with the exception of the pressure sensors having a tubular shape, mounted within the blood channel. Bullister discloses a flow-through pressure sensor in order to precisely measure fluid pressure in a chamber without affecting the flow of fluid through the chamber. The sensor 18 is attached to a flow vessel, and includes a hemocompatible cannula tube 30 through which the fluid is channeled (column 2, lines 31-39, 60-64, FIGS 1 and 2). The pressure sensor further includes a diaphragm 34 that is displaced according to the fluid pressure within the flow passage. The flexing of the diaphragm is measured by strain gauges 42 that produce an electrical voltage signal as the diaphragm is deformed under varying amounts of pressure (column 3, lines 16-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to employ the flush-mounted flow through pressure sensors disclosed by Bullister in the extracorporeal blood handling cartridge disclosed by Flank in order to measure the pressure of the fluid flowing through the passageways without disturbing actual fluid flow, as taught by Bullister. Furthermore, there is no size limit directed to the pressure sensor disclosed by Bullister, and the

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pressure sensor may be adapted to measure the pressure within a cylindrical blood filter, such as that disclosed by Flank. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to adapt the pressure sensor disclosed by Bullister to measure the pressure of blood flowing through the filter in the system disclosed by Flank, since changing the size of a recited component involves only routine skill in the art.

With regard to claim 7, Flank discloses the connection of the hemofilter/dialyzer with the blood cartridge, but not mounted to the cartridge. It would have been obvious to one of ordinary skill in the art at the time of invention to move the hemofilter/dialyzer to a location on the cartridge, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

With regard to claim 14, the modified Flank/Bullister device fails to disclose a third pressure sensor located in the blood return passage. However, It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

9. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,838,865 to Flank et al in view of US 6,171,253 to Bullister et al in view of US 4,229,299 to Savits et al. The modified Flank device discloses the apparatus as claimed with the exception of transparent blood passages and the pressure sensor embedded in the filter. Savits discloses a pump means for dialysis treatment with tubing that forms blood passageways and a filtration device. The use of transparent tubing for blood processing machines is well known in the art of extracorporeal blood treatment, and is

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incorporated in the Savits device (column 8, lines 32-35). Therefore, it would have been obvious to one of ordinary skill in the art to provide the modified Flank extracorporeal blood processing device with conventional transparent tubing in order to monitor the flow of blood through the system. Furthermore, Savits discloses the use of a hollow-fiber blood filter, which is well known in the art of blood treatment, and allows for removal of impurities from the blood (column 5, lines 4-7). The tubular pressure sensor disclosed by Bullister is capable of measuring fluid through any tubular conduit, and may be reduced in size in order to be incorporated within the hollow fiber of a semipermeable filter in order to measure the pressure of the diasylate fluid flowing within the hollow fibers of the Savits blood filter. Therefore, it would have been obvious to one of ordinary skill in the art to use the hollow fiber filter disclosed by Savits in the modified Flank device in order to allow the tubular pressure sensor disclosed by Bullister to measure the pressure of the fluid flowing through the filtration fluid side of the blood processing circuit, without adversely affecting the flow thereof, as taught by Bullister.

Response to Arguments

10. Applicant's arguments with respect to claims 1, 4, and 7 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments filed 10 September 2002 have been fully considered but they are not persuasive. In response to applicant's argument that the applied art does not apply to disposable pressure sensors, a recitation of the intended use of the claimed

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invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). As such, the applied art teaches the combination of flow-through pressure sensors on blood handling cartridges.

12. In response to applicant's argument that the combined references do not suggest overcoming the problems in the prior art identified by applicant, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the


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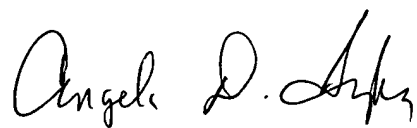
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

lrd 
November 4, 2002



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
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